K062571

PREMARKET NOTIFICATION 510(k) SUMMARY

1. Submitted by: Michael G. Farrow, Ph.D., Consultant
4239 32nd Road, South
Arlington, VA 22206
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E-mail: farrow002@yahoo.com

NOV 2 1 2006

2. Contact Person: Michael G. Farrow, Ph.D. (Official Correspondent)

3. Name of the Device:

a. Trade Name: Longport™ Episcan I-200
b. Common Name: Ultrasound Scanner
c. Classification Name: Class II 90 IYO
System, Imaging, Pulsed Echo, Ultrasonic

4. Legally Marketed Device(s) for which we are claiming substantial equivalence:

Longport LDS-1
Longport Inc.
Spring Valley Business Park
2 Braxton Way, Suite 111
Glen Mills, PA 19342

Hudson 2020, 2040, 2060 Ultrasound Scanner
Hudson Diagnostic Imaging, LLC
610 Boulevard
Elmwood, NJ

Diasus, Diagnostic Ultrasound System
P75LHF, 5-12MHz Ultra wideband Linear Array Probe
Dynamic Imaging Limeted
9 Cochrane Square, Brucefield Industrial Part
Livingston EH 54 9DR, Scotland, UK

Cortex DermaScan C Ultrasonic Transducer
Cortex DermaScan C Ultrasonic System
Textilvaeget 1
9560 Hadsund, Denmark

5. Description of the Device:

The Episcan I-200 has been developed to examine the human skin and the first few centimeters of underlying soft tissue using ultrasound of center frequency 20 MHz. The system displays the information obtained in the form of brightness or B-scans, which are presented either color-coded or grayscale images. These images can be stored on magnetic media, printed or transferred electronically for archive or analysis. Physically, the system consists of two main components: the hand-held ultrasound probe and the portable instrument/computer body with its monitor and keyboard. Operation of the Episcan I-200 is similar to that of most medical diagnostic ultrasound systems in clinical use today. The near real-time imaging of the scanner allows you to view the scanner's screen as you reposition the probe and alter the scanner's parameters. The image can be saved to a disk, printed, forwarded via a network or modem to a remote location or discarded. The Episcan I-200 contains enhancements or new features including short cut menus; adjust and move measurements and annotations; copy and paste measurements and annotations, tidy and repair databases, and new analysis functions.

6. Intended Use of the Device: Current indication for use:

"High resolution ultrasound imaging for wounds, superficial musculoskeletal diagnosis and assessment, plastic/reconstructive surgery planning and assessment, dematological assessment and diagnosis, and aesthetic application"

7. Summary of Technological Characteristics compared to Predicate Device:

Technological characteristics of this device which are similar to those of the predicates are:

1) Transducer Center Frequency
2) Scanning Mode
3) Scan Field/Length
4) Transducer stand-off medium
5) Water Reservoir retention
6) Windows Operating System
7) Operator Control
8) Data Format
9) Data Storage
10) Distance Measurement
11) Split Screen Features

12) Palattes
13) Safety
14) Power Requirement
15) Power Consumption
16) Operating Temperature and Humidity

Technological characteristics of this device which are different than those of the predicates are:

1) Transducer type
2) Scan rate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Longport, Inc.
% Michael Farrow, Ph.D.
Consultant
4239 32nd Road, South
ARLINGTON VA 22206

NOV 2 1 2006

Re: K062571
Trade Name: Longport Model Episcan I-200, Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: November 13, 2006
Received: November 13, 2006

Dear Dr. Farrow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Longport Model Episcan I-200, Ultrasound System as described in your premarket notification:

Transducer Model Number

1030-20, 20 MHz (10-30MHz)
0931-12, 20MHz (9-31MHz)

0931-10, 20MHz (9-31MHz)
0931-07, 20 MHz (9-31MHz)
1248-07 30 MHz (12-48MHz)
1248-10, 30 MHz (12-48MHz)
1248-12, 30 MHz (12-48MHz)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled,

"Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang at (240) 276-3666.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

The EPISCAN I-200 high resolution ultrasound system is a specialized system for imaging the skin and underlying soft tissue. It is intended for use by clinicians, or under the direction of physicians for imaging and analysis in research environments as well as clinical settings including medical/surgical dermatology assessment and diagnosis (aesthetic and therapeutic), plastic/reconstructive surgical planning, wound assessment and management, skin assessment for pressure ulcer detection and prevention, and superficial musculoskeletal diagnosis.

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Appendix F

Diagnostic Ultrasound Indications for Use Form

Transducer Model Number 1030-20
High Resolution Probe 20mm focus transducer
Scan Length 15mm
Nominal frequency 20 MHz (10-30MHz)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	COLOR DOPPLER	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Adult Cephalic										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial	N	N								
Other (Specify)	P	P								

N=New Indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments: P= skin and underlying soft tissue.

Other N= wound management and assessment, detection and prevention of pressure ulcers, detection of deep tissue injury, burn depth assessment, differentiate edema from Lymphedema

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Appendix F

Diagnostic Ultrasound Indications for Use Form

Transducer Model Number 0931-12
High Resolution Probe 12mm focus transducer
Scan Length 15mm
Nominal frequency 20 MHz (9-31 MHz)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	COLOR DOPPLER	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Adult Cephalic										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intervascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial	N	N								
Other (Specify)	N	N								

N=New Indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments: **Other N= wound management and assessment, superficial musculoskeletal assessment, clinical dermatology, skin lesion assessment, aesthetics**

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Appendix F

Diagnostic Ultrasound Indications for Use Form

Transducer Model Number 0931-10
High Resolution Probe 10mm focus transducer
Scan Length 15mm
Nominal frequency 20 MHz (9-31 MHz)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	COLOR DOPPLER	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Adult Cephalic										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intervascular										
Peripheral Vascular										
Laparoscopic										
Muscula-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)	N	N								

N=New Indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments: Other N= wound management and assessment, superficial musculoskeletal assessment, clinical dermatology, aesthetics

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Appendix F

Diagnostic Ultrasound Indications for Use Form

Transducer Model Number 0931-07
High Resolution Probe 12mm focus transducer
Scan Length 15mm
Nominal frequency 20 MHz (9-31 MHz)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	COLOR DOPPLER	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Adult Cephalic										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)	N	N								

N=New Indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments: **Other: N= clinical dermatology, skin lesion assessment, aesthetics**

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Appendix F

Diagnostic Ultrasound Indications for Use Form

Transducer Model # 1248-07
Very High Resolution Probe 7.25mm focus transducer
Scan Length = 15mm
Nominal Frequency = 30 MHz (12 – 48 MHz)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	COLOR DOPPLER	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Adult Cephalic										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intervascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)	N	N								

N=New Indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

OTHER = Clinical Dermatology

Aesthetics

SEE ATTACHED DETAILS FOR INDICATIONS FOR USE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Appendix F

Diagnostic Ultrasound Indications for Use Form

Transducer Model # 1248-10
Very High Resolution Probe 10mm focus transducer
Scan Length = 15mm
Nominal Frequency = 30 MHz (12 – 48 MHz)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	COLOR DOPPLER	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Adult Cephalic										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intervascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)	N	N								

N=New Indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

OTHER = Clinical Dermatology

Aesthetics

SEE ATTACHED DETAILS FOR INDICATIONS FOR USE

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Appendix F

Diagnostic Ultrasound Indications for Use Form

Transducer Model # 1248-12
Very High Resolution Probe 12mm focus transducer
Scan Length = 15mm
Nominal Frequency = 30 MHz (12 – 48 MHz)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	COLOR DOPPLER	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Adult Cephalic										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intervascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)	N	N								

N=New Indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

OTHER = Clinical Dermatology

Aesthetics

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